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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,338	03/01/2004	Ajay K. Luthra	2177.16US02	9411

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EXAMINER

KRUEER, KEVIN R

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,338

Applicant(s)

LUTHRA ET AL.

Examiner

Kevin R. Krueer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-104 and 151-209 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-104 and 151-209 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 54-104 and 151-209 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant failed to point out where in the original disclosure a "copolymer that has a weight averaged molecular weight of at least about 2500" is supported. Furthermore, the examiner could not find support for said limitation.

Furthermore, claims 67, 170-189, and 206 are rejected under 35 U.S.C. 112, first paragraph because the original disclosure does not contain support for the limitation "about 26 degree Centigrade."

Claim Rejections - 35 USC § 102

3. The rejection of claims 54-75, 77, 84, 92-104, and 151-154 under 35 U.S.C. 102(e) as being anticipated by Alvarado et al (US 6,530,950) has been overcome by amendment. Said reference does not teach the newly claimed coating thickness.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 54-75, 77, 84, 92-104, 151-163, 167-182, 186-202, and 206-209 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarado et al (US 6,530,950) in view of Tartaglia et al (US 5,637,113).

Alvarado teaches a stent for insertion into a lumen wherein the stent is coated with a polymer (abstract). The polymer comprises 10-98% of a first monomer composed of an aliphatic ester C1-C50 of acrylic acid which when homogenized has a glass transition temperature lower than about 25C, and a second monomer having sites of unsaturation capable of copolymerizing with the first monomer and having a glass transition temperature of greater than 25C (col 2, lines 50+). For example, the first monomer may comprise butyl acrylate (col 2, lines 62+) and is herein relied upon to read on the claimed first copolymer. The second monomer may comprise an ester of a methacrylic acid such as butyl methacrylate (col 3, lines 1+), and is herein relied upon to read on the second monomer. The polymer may further comprise 2-40wt% polyethylene glycol methacrylate (col 3, lines 25+). Said polyethylene glycol methacrylate is herein understood to read on the claimed "third monomer unit" of claim 57. Said terpolymer is understood to be taught with sufficient specificity to teach the terpolymer of claim 69. Furthermore, since the terpolymer is taught to be a "polymer," it is understood to necessarily have a molecular weight above 2500. The polymer may comprise an alternating copolymer formed by step polymerization, random or block

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copolymer (col 7, lines 1+) and preferably has a glass transition temperature of less than 25C (col 7, lines 45+). The coating further comprises a therapeutic agent (col 14, lines 7+) such as paclitaxel (col 14, lines 30+).

With regards to the relative glass transition temperature limitations of claims 54, 60, 61, 64, 96, 97, 102, 167, and 206, the monomers taught by Alvarado inherently meets said glass transition temperature limitations because said monomers are the same as those utilized by applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable (MPEP2112.01).

With regard to claims 70 and 72, said limitations are method limitations that do not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making inherently results in a materially different product. No such showing has been made.

With regards to claims 75, 77, 84, Alvarado teaches the coating may be applied to the stent via an adhesive such as fluorinated polymers, heparin, collagen, and fibrin (col 13, lines 57+).

Alvarado does not teach the newly claimed thickness of the polymeric coating. However, Tartaglia teaches that the thickness of a drug loaded polymeric coating on a stent should be between 0.00015in-0.002in thick to prevent the profile of the stent from becoming too large. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the thickness of the coating taught in Alvarado to be between 0.00015in-0.002in. The motivation for doing so would have

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been that Tartaglia teaches such thickness are traditionally used for drug loaded polymeric coatings on stents.

6. Claims 76, 78-83, 85, 91, 164-166, 183-185, and 203-205 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarado et al (US 6,530,950) in view of Tartaglia et al (US 5,637,113), as applied to claims above, and further in view of Lentz et al (US 2002/0133183A).

Alvarado is relied upon as above, but does not teach the application of a heparin layer to said copolymer layer. However, Lentz teaches that it is well known in the art to apply heparin to coat biomaterials in order to prevent clotting (0115). Said herapin is photo-activated in order to form covalently bonds with the surface to which it is applied (0117). Thus, it would have been obvious to one of ordinary skill in the art to coat the stent taught in Alvarado with herapin in order to prevent clotting.

With respect to claim 85, the examiner takes the position that any coating will reduce the rate of release of the therapeutic agent to some extent.

7. Claims 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvarado et al (US 6,530,950) in view of Tartaglia et al (US 5,637,113), as applied to claims above, and further in view of Sahatjian et al (US 5,843,089).

Alvarado is relied upon as above, but does not teach coating said stent with an acrylic, vinyl alcohol, or polyvinyl pyrrolidone coating. However, Sahatjian teaches lining a stent with a hydrogel in order to reduce shear forces and flow disturbances in the bloc, protect, damaged cells adjacent to the stent, and reduce platelet deposition. Said hydrogel may comprise, an acrylate, polyvinyl pyrrolidone, or PVOH. Thus, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to apply any of said hydrogels to the stent taught in Alvarado. The motivation for doing so would have been to reduce shear forces and flow disturbances in the bloc, protect, damaged cells adjacent to the stent, and reduce platelet deposition.

Response to Arguments

Applicant's arguments filed March 20, 2006 have been fully considered but they are not persuasive.

Applicant argues Alvarado does not specify a thickness and therefore does not supply all of the claimed elements. The examiner agrees but notes Alvarado is not relied upon to meet said limitation. Rather, Tartaglia is relied upon to motivate the skilled artisan to select the claimed thickness. Applicant argues the "molded cylinder" teaching of Alvarado (col 13, line 22) suggest that the polymers should be applied thickly enough to form a molded cylinder, which points to a thickness of polymer greater than the claimed range. Said argument is noted, but there is no evidence of record that demonstrates said teaching constitutes a teaching away from the presently claimed thickness. Thus, applicant's argument is not persuasive.

With respect to independent claim 151, applicant argues Alvarado teaches that only rigid regions of a stent are to be coated, and not the flexible regions. The examiner notes the rigid portions of Alvarado are minimally flexible in the radial dimension (col 4, lines 38-42) and will expand do expand radially in a plastic manner (see US 6,224,625-background of the invention). Thus, Alvarado is understood to read on the claimed

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invention wherein the coating is applied to a portion of every expandable portion of an expandable stent.”

With respect to independent claim 170, Applicant argues Alvarado teaches that the polymer should have a glass transition temperature of below 25 whereas the claims call for a glass transition temperature of about 26 to about 40. The examiner maintains the position that Alvarado reads on the claimed invention because below 25 (herein understood to include all points below 25C) reads on about 26C, since the claimed range includes temperatures lower than 26C.

With respect to claim 190, Applicant argues the medical devices claimed therein are not taught or suggested in Alvarado. The examiner respectfully disagrees.

Alvarado reads on the claimed “expandable stent.”

With respect to the 103(a) rejections of claims 76,78-83, 85, and 91 in light of Alvarado in view of Lentz and claims 86-90 in light of Alvarado in view of Sahatijian, Applicant argues the claims are allowable because of the above noted argued deficiencies of Alvarado. Said argument is not persuasive for the reason noted above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin R. Kruer whose telephone number is 571-272-1510. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin R. Kruer
Patent Examiner-Art Unit 1773